

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of telephone follow up on pregnancy outcome and general health of mothers with Gestational Diabetes

Protocol summary

Summary

Background: Gestational diabetes is associated with a number of maternal and neonatal adverse outcomes. The prevalence of GDM has risen 122% in the last 20 years. There is evidence of bidirectional link between mental health problems and gestational diabetes. The aim of this study was to determine the effect of telephone follow up on pregnancy outcome and general health of mothers with gestational diabetes. Methods: This study was a clinical trial in which 80 mothers with gestational diabetes who were referred to prenatal clinic of Imam Khomeyni Hospital in Tehran. The inclusion criteria was include Age between 18-45 years, Singleton pregnancy, Not taking medication that increase blood glucose such as corticosteroids, Having phone at home, Not having speech and hearing problems, Being able to speak Persian language and understand it, Lack of chronic diseases, No history of infertility or ART No history of diabetes in pre pregnancy, Having at least read and write. Exclusion criteria was consist of Not respond to phone calls (more than one contact), The condition that increase blood sugar such as stress, death of relatives and take steroids and other drug, Preterm labor, Use of any diet and medication during study. They were randomly divided into intervention and control group. Data collection tools was including phone, Exicheck, demographic form, check list of telephone follow up and GHQ questionnaire. Data were collected at baseline (28 weeks of pregnancy) and 6 weeks after delivery. Telephone follow up was applied for the experimental group in the field of adherence of diet, insulin injections, lab tests and remembering later visit for 10 weeks. In addition, the questions of mothers about pregnancy, diabetes and general health were answered. Data analysis was done using SPSS and descriptive and analytic statistics (independent t-test, paired t-test, mann-whitaney and chi square) were used where appropriate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904143037N3**

Registration date: **2012-06-06, 1391/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-06, 1391/03/17

Registrant information

Name

Mehrnaz Geranmayeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 1669

Email address

geranmay@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2011-07-11, 1390/04/20

Expected recruitment end date

2012-01-10, 1390/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of telephone follow up on pregnancy outcome and general health of mothers with Gestational Diabetes

Public title

Telephone Follow up and Gestational Diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18-45 years Singleton pregnancy Not taking medication that increase blood glucose such as corticosteroids Having phone at home Not having speech and hearing problems Being able to speak Persian language and understand it Lack of chronic diseases No history of infertility or ART No history of diabetes in pre pregnancy Having at least read and write Exclusion Criteria: Not respond to phone calls (more than one contact) The condition that increase blood sugar such as stress, death of relatives and take steroids and other drug Preterm labor Use of any diet and medication during study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science

Street address

Tehran Keshavarz Blvd Ghods Street

City

Tehran

Postal code**Approval date**

2011-07-03, 1390/04/12

Ethics committee reference number

13165

Health conditions studied**1****Description of health condition studied**

Gestational Diabetes

ICD-10 code

xv

ICD-10 code description

z35

Primary outcomes**1****Description**

Measuring blood Sugar

Timepoint

28,32 and 36 weeks of pregnancy

Method of measurement

Exicheck

Secondary outcomes**1****Description**

Outcome pregnancy and General health

Timepoint

Before and after intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

Telephone follow up in order to adherence to diet, insulin injections, doctor prescribed, doing lab test and also to remind the next visit and answering patient's questions about pregnancy, diabetes and general health.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Prenatal clinic of Imam Khomeyni Hospital

Full name of responsible person**Street address**

Tehran Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Esmat Karimi

Street address

Tehran Keshavarz Blvd ghods Street University of
central building Sixth floor

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Tehran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Mehrnaz Geranmayeh

Position

Master of Science

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty